Amendments to the Claims

This listing of claims will replace all prior versions and listings in this application.

Listing of Claims

1. (Currently Amended) A method of altering a specific immune response to ~~an~~ one or more antigen(s) in an individual sensitized to ~~the~~ said antigen comprising:

i) determining that an individual has an immune response when challenged with one or more antigen(s);

ii) administering orally to ~~the~~ said individual an effective amount of ~~the~~ said antigen(s) in immunotherapeutic form, wherein said administration of said antigen(s) down regulates the immune response ~~is down regulated~~; and

iii) subsequently administering parenterally to ~~the~~ said individual an effective amount of an immunomodifying agent comprising ~~the~~ said antigen in immunogenic form.

2. (Withdrawn) A method according to claim 1, wherein the immunomodifying agent further comprises either a TH1 or TH2 adjuvant, wherein the adjuvant normally induces the type of TH-response which is the target of the immunotherapy.

3. (Currently Amended) ~~A~~ The method ~~according to~~ of claim 1, wherein the immunotherapy is targeted at the specific immune response.

4. (Currently Amended) ~~A~~ The method ~~according to~~ of claim 1, wherein the effective amount in step ii) is one or more doses of said antigen in immunotherapeutic form.

5. (Currently Amended) ~~A~~ The method ~~according to~~ of claim 1, wherein said antigen in immunotherapeutic form further comprises agents designed to modulate the specific immune responses.

6. (Currently Amended) ~~A~~ The method ~~according to~~ of claim 1 , wherein the alteration to the specific immune response is attenuation of the TH-response component, which is associated with expression of the disease being treated.

7. (Currently Amended) ~~A~~ The method ~~according to~~ of claim 1, wherein the alteration to the specific immune response is conversion of the TH1 component of the response to a TH2 component or conversion of the TH2 component to a TH1 component.

8. (Currently Amended) ~~A~~ The method ~~according to~~of claim 1, wherein the alteration to the specific immune response is reversing the ratio between the TH1 and TH2 components of the response.

9. (Withdrawn) A method according to claim 8, wherein the immune response in an untreated individual comprised high level production of TH1 cytokines and low level production of TH2 cytokines is reversed following treatment.

10. (Currently Amended) ~~A~~ The method ~~according to~~of claim 8, wherein the immune response in an untreated individual ~~comprised~~ which comprises high level production of TH2 cytokines and low level production of TH1 cytokines is reversed following treatment.

11. (Withdrawn) A method of treating a TH1-associated disease comprising:

i). administering to an individual in need thereof an effective amount of an antigen in immunotherapeutic form; and

ii). subsequently administering to the individual an effective amount of an immunomodifying agent comprising said antigen in immunogenic form, wherein the antigen specific TH1 response in the individual is reduced relative to the specific TH1 response before administration of said immunomodifying agent.

12. (Withdrawn) A method according to claim 11, wherein the immunomodifying agent further comprises a TH1 adjuvant.

13. (Withdrawn-Currently Amended) A method of treating a TH2-associated disease selected from the group consisting of allergic atopic disorders, allergic asthma, atopic dermatitis and allergic rhinitis, said method comprising:

i). determining that an individual has an antigen specific TH2 immune response when challenged with an antigen;

ii). administering orally to ~~an~~ said individual ~~in need thereof~~ an effective amount of ~~an~~ one or more antigen(s) in immunotherapeutic form; and

iii). subsequently administering parenterally to ~~the~~ said individual still under the effects of immunotherapy an effective amount of an immunomodifying agent comprising

said antigen(s) in immunogenic form ~~and a TH2 adjuvant~~, wherein ~~the~~ said antigen specific TH2 response in ~~the~~ said individual is reduced relative to ~~the~~ said specific TH2 response before administration of said immunomodifying agent.

14. (Withdrawn) A method according to claim 13, wherein the immunomodifying agent further comprises a TH2 adjuvant.

15. (Withdrawn) A method of treating a disease associated with a mixed TH1 and TH2 immune response comprising:

i). administering to an individual in need thereof an effective amount of an antigen in immunotherapeutic form; and

ii). subsequently administering to the individual an effective amount of an immunomodifying agent comprising said antigen in immunogenic form which boosts both TH1 and TH2 immunity, wherein ensuing specific TH1 and TH2 responses in the individual are reduced relative to the specific TH1 and TH2 responses before administration of said immunomodifying agent.

16. (Withdrawn) A method according to claim 15, wherein the immunotherapeutic form in step i) is sublingual administration of antigen.

17. (Withdrawn) A method according to claim 15, wherein the immunomodifying agent in step ii) is administered parenterally.

18. (Withdrawn) A method according to claim 15, wherein the immunomodifying agent further comprises either an adjuvant which boosts both TH1 and TH2 immunity or a mixture of TH1 and TH2 adjuvants, wherein ensuing specific TH1 and TH2 responses in the individual are reduced relative to the specific TH1 and TH2 responses before administration of said immunomodifying agent.

19. (Currently Amended) A method according to claim 1, wherein ~~the immunotherapy is~~step (ii) comprises administration to an individual ~~in need thereof~~ an effective amount of one or more antigen(s) in immunotherapeutic form, wherein the antigens are associated with expression of pathogenic TH2 immunity.

20. (Withdrawn) A method according to claim 1, wherein the individual suffers from a TH1-associated disease and the antigen in immunotherapeutic form is predominately a TH1-specific antigen.

21. (Withdrawn-Currently Amended) A method of treating a TH2-associated disease selected from the group consisting of allergic atopic disorders, allergic asthma, atopic dermatitis and allergic rhinitis comprising:

i). determining that an individual has an antigen specific TH2 immune response when challenged with one or more antigen(s);

ii). administering orally to ~~an~~ said individual ~~in need thereof~~ an effective amount of ~~an~~ one or more antigen(s) in immunotherapeutic form, wherein said immune response to said disease is down regulated; and

iii). subsequently administering parenterally to ~~the~~ said individual still under the effects of immunotherapy an effective amount of an immunomodifying agent comprising said antigen(s) in immunogenic form ~~and a TH2-adjuvant~~.

22. (Withdrawn) A method according to claim 21, wherein the immunomodifying agent further comprises either a TH1 or TH2 adjuvant, wherein the adjuvant normally induces the type of TH-response which is the target of the immunotherapeutic form of the antigen.

23. (Withdrawn) A method according to claim 21, wherein the disease is a TH1-associated disease selected from the group consisting of rheumatoid arthritis, multiple sclerosis, thyroiditis, Crohn's disease, systemic lupus erythematosus, experimental autoimmune uveoretinitis, experimental autoimmune encephalitis, insulin dependent diabetes mellitus, contact dermatitis and chronic inflammatory disorders.

24. (Withdrawn) A method according to claim 21, wherein the disease is a TH2-associated disease selected from the group consisting of allergic atopic disorders, allergic asthma, atopic dermatitis, hyper-IgE syndrome, Omenn's syndrome, and allergic rhinitis.

25. (Withdrawn) A method according to claim 2, wherein the TH2 adjuvant is selected from the group consisting of alum, pertussis toxin, lacto fucopentaose III, and phosphopolymer or combinations thereof.

26. (Withdrawn) A method according to claim 2, wherein the TH1 adjuvant is selected from the group consisting of complete Freund's adjuvant, monophosphoryl lipid A, 3-de-O-acylated monophosphoryl lipid A (3D-MPL), aluminum salt, CpG-containing oligonucleotides, immunostimulatory DNA sequences, saponin, Montanide ISA 720, SAF, ISCOMS, MF-59, SBAS-3, SBAS-4, Detox, RC-529, aminoalkyl glucosaminide 4-phosphate, and LbeIF4A.

27. (Currently Amended) ~~A~~ The method ~~according to~~of claim 1, wherein ~~the~~ said individual is a mammalian animal.

28. (Currently Amended) ~~A~~ The method ~~according to~~of claim 27, wherein ~~the~~ said mammalian animal is a dog, a cat, a livestock animal, a primate or a horse.

29. (Currently Amended) ~~A~~ The method ~~according to~~of claim 27, wherein ~~the~~ said mammalian animal is a human.

30. (Withdrawn) A kit used for altering TH1 or TH2 response phenotype in an individual in need thereof comprising:

i). one or more TH1 antigen(s); or

ii). one or more TH1 or TH2 adjuvant(s); or

iii). combinations thereof; and

iv). instructions for use.

31. (Currently Amended) A method of immunotherapy comprising:

i). determining that an individual has an immune response when challenged with one or more antigen(s);

ii). administration to ~~an~~ said individual ~~in need thereof~~ a plurality of antigen shots;

iii). administration to said individual less than five individual shots of said antigen combined with one or more TH1 and/or TH2 adjuvant(s);

wherein the antigen shots of step (ii) are administered orally and the antigen shots of step (iii) are administered parenterally.

32. (Currently Amended) ~~A~~ The method ~~according to~~ of claim 31, wherein ~~the~~ said individual shots of said antigen(s) combined with TH1 and/or TH2 adjuvant ~~is~~ are less than three.

33. (Currently Amended) ~~A~~ The method ~~according to~~ of claim 31, wherein ~~the~~ said individual shots of said antigen combined with TH1 and/or TH2 adjuvant ~~is~~ are one.

34-49. (Cancelled)

50. (Withdrawn) An immunomodifying agent comprising at least one antigen in immunogenic form and at least one adjuvant, wherein the adjuvant normally induces the type of TH-response associated with the disease caused by said antigen.

51. (Withdrawn-Currently Amended) ~~A~~ The method ~~according to~~ of claim 13, wherein ~~the~~ said antigen(s) administered in immunogenic form ~~of the antigen will be~~ is/are administered subcutaneously and ~~the~~ said antigen(s) administered in immunotherapeutic form is/are administered sublingually.

52. (Cancelled) The method of claim 13, wherein oral administration is sublingual administration.

53. (Cancelled) The method of claim 13, wherein the antigen is a mite antigen from *Dermatophagoides pteronyssinus, Dermatophagoides farinae or Blomia tropicalis.*

54. (Cancelled) The method of claim 13, wherein the antigen is a pollen or grass allergen.

55. (Cancelled) The method of claim 13, wherein the TH2 adjuvant is selected from the group consisting of alum, pertussis toxin, lacto fucopentaose III, and phosphopolymer or combinations thereof.

56. (Cancelled) The method of claim 13, wherein the individual is a mammalian animal.

57. (Cancelled) The method of claim 21, wherein oral administration is sublingual administration.

58. (Cancelled) The method of claim 21, wherein the antigen is a mite antigen from *Dermatophagoides pteronyssinus, Dermatophagoides farinae or Blomia tropicalis.*

59. (Cancelled) The method of claim 21, wherein the antigen is a pollen or grass allergen.

60. (Cancelled) The method of claim 21, wherein the TH2 adjuvant is selected from the group consisting of alum, pertussis toxin, lacto fucopentaose III, and phosphopolymer or combinations thereof.

61. (Cancelled) The method of claim 21, wherein the individual is a mammalian animal.

62. (New) A method of treating a TH2-associated disease selected from the group consisting of allergic atopic disorders, allergic asthma, atopic dermatitis and allergic rhinitis, said method comprising:

i). determining that an individual has an antigen specific TH2 immune response when challenged with one or more antigen(s);

ii). administering orally to said individual an effective amount of said antigen(s) in immunotherapeutic form; and

iii). subsequently administering parenterally to said individual still under the effects of immunotherapy an effective amount of an immunomodifying agent comprising said antigen(s) in immunogenic form and a TH2-adjuvant, wherein said antigen specific TH2 response in said individual is reduced relative to the specific TH2 response before administration of said immunomodifying agent.

63. (New) The method of claim 62, wherein oral administration is sublingual administration.

64. (New) The method of claim 62, wherein said immunogenic form of said antigen will be administered subcutaneously and said immunotherapeutic form is administered sublingually.

65. (New) The method of claim 62, wherein said antigen is a mite antigen from *Dermatophagoides pteronyssinus, Dermatophagoides farinae or Blomia tropicalis*.

66. (New) The method of claim 62, wherein said antigen is a pollen or grass allergen.

67. (New) The method of claim 62, wherein said TH2 adjuvant is selected from the group consisting of alum, pertussis toxin, lacto fucopentaose III, and phosphopolymer or combinations thereof.

68. (New) The method of claim 62, wherein said individual is a mammalian animal.

69. (New) A method of treating a TH2-associated disease selected from the group consisting of allergic atopic disorders, allergic asthma, atopic dermatitis and allergic rhinitis comprising:

i). determining that an individual has an immune response when challenged with an antigen;

ii). administering orally to said individual an effective amount of said antigen in immunotherapeutic form, wherein the immune response to said disease is down regulated; and

iii). subsequently administering parenterally to said individual still under the effects of immunotherapy an effective amount of an immunomodifying agent comprising said antigen in immunogenic form and a TH2-adjuvant.

70. (New) The method of claim 69, wherein oral administration is sublingual administration.

71. (New) The method of claim 69, wherein said immunogenic form of said antigen will be administered subcutaneously and the immunotherapeutic form is administered sublingually.

72. (New) The method of claim 69, wherein said antigen is a mite antigen from *Dermatophagoides pteronyssinus, Dermatophagoides farinae or Blomia tropicalis.*

73. (New) The method of claim 69, wherein said antigen is a pollen or grass allergen.

74. (New) The method of claim 69, wherein said TH2 adjuvant is selected from the group consisting of alum, pertussis toxin, lacto fucopentaose III, and phosphopolymer or combinations thereof.

75. (New) The method of claim 69, wherein said individual is a mammalian animal.